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Mobile Health (m-Health) for diabetes management

Robert SH Istepanian, Donatella Casiglia, John W Gregory

ABSTRACT

Diabetes is a major health challenge with a global impact regardless of age, country or economic condition. The increased prevalence of diabetes is reaching alarming levels. The necessity and urgency to find innovative care delivery solutions is becoming more important, particularly in the digital age. It is expected in the near future that more people with diabetes, especially the younger generations will be empowered by their smartphones and relevant mobile health (m-Health) innovations, to take more responsibility of their condition. Clinicians and healthcare providers are increasingly likely to assume the role of 'navigators' and 'advisors' rather than simply the medical gatekeeper for their patients. In this article, we describe the general architecture of current m-Health systems and applications for diabetes management. We also discuss the clinical evidence for impact from these important and innovative approaches to diabetes self-care and management and likely future trends in their usage. The latest statistics indicate that there are more than 1200 diabetes smartphone 'apps' and this area is growing exponentially in terms of ideas, technologies, devices and the associated industry. M-Health for diabetes care is now a major business stream for the medical device, mobile phone and IT telecommunication industries with high expectations arising from the potential benefits to be gained by both patients and healthcare providers. However, this potential has not yet been fully developed on the clinical side. This may be due to many factors including the reluctance of clinicians to engage with these technologies due to the lack of clinical evidence for their efficacy, poor adherence of people with diabetes to longterm use of these apps and the reluctance of healthcare funders to reimburse mobile diabetes.

Key Words: Diabetes • Self-management • Mobile health • m-Health

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Diabetes mellitus is a major global chronic disease that affects an estimated 415 million adults globally. With an additional 318 million adults with impaired glucose tolerance, they are at high risk of developing comorbidity in the future, including heart disease, end-stage renal failure and the single biggest cause of preventable blindness, as well as other causes of premature mortality (International Diabetes Federation, 2015).

The economic burden of diabetes is increasing globally, both in developing and developed countries. These alarming statistics represent major opportunities—but also challenges—for mobile health (m-Health) systems designed and developed for not only the management of but also the prediction of diabetes in different healthcare delivery settings.

Figure. 1 Impact of intensive therapy of major diabetes RCT and summary of complications (adapted from Inzucchi et al, 2015)

In clinical terms, diabetes is associated with risk of long term complications (Inzucchi et al, 2015). The most common macrovascular complications include coronary artery disease and cerebrovascular disease, while for the microvascular complications, retinopathy, neuropathy and chronic kidney disease are the most common. These complications result from metabolic abnormalities, including hyperglycemia, elevated levels of free fatty acids, and insulin resistance.

Figure 1 summarises the outcomes of major randomised controlled trials (RCTs) as published by the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD) (Inzucchi et al, 2015). These results indicated that intensive glycemic control in both type 1 (T1D) and type 2 (T2D) diabetes prevents or delays microvascular complications, specifically retinopathy and albuminuria. However, the data from these trials concerning the glucose control and macrovascular complications were more complex and overall neutral (Inzucchi et al, 2015).

To alleviate these uncertainties and provide further evidence on the role of m-Health technologies to reduce complications, the concept of mobile diabetes self-management has become an important element of diabetes care in recent years (Istepanian and Woodward, 2017). For more than two decades, many innovative mobile health approaches for promoting diabetes self-care have been increasingly adopted including:

- Providing support for self-management strategies, especially in T2D
- Use of new m-Health technological approaches for better patient education enabling new integrated diabetes care models that embrace these new technological developments and solutions (Istepanian and Woodward, 2017).

Over the last decade or so, clinicians and users have become confused about the differences between the four pillars of IT for healthcare (telemedicine, telehealth, e-health and m-Health) and how these might be applied to diabetes care (Istepanian and Woodward, 2017). During this period, numerous studies of telehealth and telemedicine were conducted evaluating the clinical effectiveness and impact of these systems for diabetes management (Istepanian, 2015). However, overall these studies provided conflicting evidence for the clinical and cost-effectiveness of these approaches. Since 2007, diabetes management using smartphone technologies has become one of the most prolific areas of m-Health research and development. This is reflected in numerous pilot studies and the proliferation of hundreds of commercial diabetes apps and mobile self-management systems (Istepanian, 2015; Istepanian and Woodward, 2017). However, this commercial interest has not yet translated to clinical practice. This may be due to many factors, including reluctance of clinicians to engage in the use of

such technologies due to their perception of a lack of clinical evidence for benefit; the poor adherence of people with diabetes to the long-term use of apps; and the reluctance of commissioners of healthcare to reimburse mobile diabetes solutions. This can be attributed to several factors such as the diversity of the existing economic and service reimbursement models. These are mostly based on the USA healthcare model of m-Health reimbursement 'by the yard' billing approach. These models clearly are inapplicable to low resource settings and require more frugal approaches. Further, there is no clear regulatory framework for m-Health in diabetes, considering the potential impact of these systems globally.

From the clinical perspective, these pilot studies have indicated promising but uncertain outcomes, especially with respect to improving blood glucose control (glycosylated haemoglobin (HbA1c)) until more recently (Istepanian and Woodward, 2017). Although there is a major global market for the potential integration of m-Health into diabetes care, there is no largescale or definitive long-term study—either planned or implemented—to validate the clinical effectiveness of these technologies and their impact on diabetes self-care and management.

m-Health for diabetes self-management

The use of smartphones for diabetes self management has seen massive interest in the last decade, since the inception of the first smart phone in 2007. In the last decade several RCTs been conducted to provide the necessary clinical evidence for the validity of this approach to diabetes care. Although results from these trials have produced outcomes with uncertain clinical implications, there is increasing evidence and consensus that these technologies and their associated smartphone apps can be an effective approach and a supplementary support to standard diabetes self-management. However, much research remains to be undertaken in this area to provide better clinical evidence for the potential benefits arising from this technology— particularly in parts of the world with poor resources, where the prevalence of diabetes is high.

The infrastructure that underpins m-Health for diabetes self-management is shown in Figure 2 (Istepanian and Woodward, 2017). The basic functions of a smartphone-based diabetes selfmanagement system adhere to the following principles:

- To empower people with diabetes to self-monitor blood glucose (SMBG) or other variables when and as needed (e.g. blood pressure, weight, and diet)
- To engage people in the management of their diabetes by promoting self-efficacy
- To achieve pre-set care targets and to provide interactive feedback between patients and physicians with respect to disease progress and adherence to therapy
- To allow physicians to facilitate patient self-care, to improve outcomes with potential cost savings (Istepanian and Woodward, 2017).

This intervention and architecture consist of three basic modules: mobile patient end; healthcare provider or clinician end; and remote data servers or clouds, which host the patient electronic health record (EHR), together with data analytics, inference engine files (for artificial intelligence) and system controllers. These servers are usually hosted in secure locations. The mobile patient and physician's ends are usually connected via the mobile network or other internet connectivity channels (e.g. WiFi) to transfer the blood glucose readings (and other data such as about diet and exercise) to the remote server for further processing and feedback. A brief summary of these functions is described next for completeness. Further details on the technical development of these systems are described elsewhere (Istepanian and Woodward, 2017).

As shown in Figure 2, the general architecture of m-Health diabetes self-management and care systems consist of the following modules:

Figure 2. General architecture of m-Health diabetes self-management and care system (adapted

- The patient end, which consists of a smartphone equipped with a special diabetes app connected wirelessly via Bluetooth to a blood glucose meter and used for tracking and storing the patient's daily blood glucose data and status. Hypertensive individuals with diabetes may also be given a wireless blood pressure device and weight scales as required. From Istepanian and Woodward, 2017) The patient is then required to complete basic training and an educational programme on using these systems
- The acquired blood glucose data are usually transmitted wirelessly via the individual patient's smart phone and stored in a remote portal hosted in a health clinic or hospital. This portal consists of the patient's EHR, supported with intelligent data analytic tools that can process the data and produce simple illustrative graphics. These can be accessed and viewed by the patient and physician via two separate web portals, each designed and developed for separate access. The graphics provide information and decision support messages, such as lifestyle change, educational notes, and medication required to improve the patient's daily management routine
- The adaptation of any medication and treatment plans required for individual patients. This is based on their selfmanagement history, daily blood glucose profiles, treatment progress, and designated therapy protocol plans assessed regularly at 3–6 month follow-up intervals.

The schedule and frequency of taking daily blood glucose readings and other medical data are dependent on the individual care plan made for each patient by their specialist and based on their individual diabetes type, treatment and progress. The timings of these readings are usually programmed in the patient's smartphone app as reminders to take readings according to pre-set schedules.

Smart devices, such as continuous glucose monitors and continuous subcutaneous insulin infusion pumps used by people with T1D can also communicate wirelessly to their smartphones for monitoring purposes. Patients are usually required to test their blood glucose concentrations several times daily, usually before meals and 2–4 hours after meals. It is likely that new generations of wireless diabetes monitoring products will be increasingly available in the near future.

The patient empowerment process is embodied by these systems in many aspects, allowing them to view variations in their blood glucose levels on their mobile phones—daily, weekly or as needed. Apps with specific software are programmed to alert patients to their lifestyle and treatment choices, as well as helping them to monitor for potential hypoglycaemic or hyperglycaemic episodes. In some apps it is possible to track average glycemia for real-time estimation of HbA1c levels derived from SMBG data. It must be emphasised that there are many efficacy, safety and regulatory challenges associated with apps developed for mobile diabetes selfmanagement (Istepanian, 2015).

Recent reviews of the use of smartphone apps for diabetes care indicate the majority of these apps focus on health tracking (e.g. blood glucose, insulin dose and carbohydrate intake), requiring manual entry of the blood glucose measurement and relevant health data. More recent developments in newer blood glucose meters allow the automatic transmission of the blood glucose data and measurements to be transferred to an app using seamless wireless Bluetooth connectivity (Istepanian and Woodward. 2017). However, the interoperability of the different blood glucose devices with

different smartphone operating systems, in addition to their incompatibility of connecting different blood glucose meters with a unified web-based platforms, is still an ongoing challenge.

Clinical effectiveness of m-Health interventions

The prevention of hypoglycemic episodes has been identified as an important objective in diabetes management with SMBG. It has been increasingly proven to provide better diabetes management and prevention of both acute and chronic complications of diabetes, particularly for self-regulatory prevention of significant hypoglycemic episodes (Schutt et al, 2006; Garg and Hirsch, 2015). Although the value of SMBG for those with T2D remains debatable, continuous glucose monitoring is approved as an adjunct to SMBG (Garg and Hirsch, 2015).

The patient representative charity Diabetes UK recommends that SMBG be advised in people receiving sulphonylurea and prandial glucose regulatory therapies because of the risk of hypoglycemia in these groups (Diabetes UK, 2013). By contrast, the role of SMBG in self-management of those with T1D is less controversial, and the literature generally supports SMBG to achieve better glucose control in T1D (Garg and Hirsch, 2015). From the clinical perspective, the results of a large multicentre study including 24 500 patients from 191 centres in Germany and Australia showed that frequent SMBG is associated with better metabolic control in both those with T1D and T2D (Schutt et al, 2006).

More recently, there has been an increase in the numbers of published clinical pilot studies and formal RCTs to evaluate different mobile platforms for the management of T1D, T2D, and gestational diabetes (Istepanian and Woodward, 2017). These and more recent reviews provide a clearer picture of the clinical evidence that these technologies may be effective in supporting diabetes care and self-management (Liang et al, 2011; Hou et al, 2016; Cui et al, 2016). A metaanalysis of 22 trials conducted between 2005 and 2009 with a total of 1657 participants showed that mobile phone interventions reduced HbA1c levels by a mean of 0.5% (6 mmol/mol; 95% confidence interval, 0.3–0.7% (4–8 mmol/mol)) over a median of 6 months follow-up duration. A further sub-group analysis of 11 studies among those with T2D showed reductions in HbA1c that were more significant compared to studies in those with T1D (0.8% (9 mmol/mol) and 0.3% (3 mmol/mol) respectively; $p = 0.02$) (Liang et al, 2011).

Another recent review and meta-analysis analysed the outcomes of 14 clinical RCTs in both T1D and T2D ($n = 1360$) (Hou et al, 2016). This study concluded that all the T2D studies reported reductions in HbA1c levels with a mean reduction using the mobile phone app compared to the control groups of 0.49%. It particularly noted that younger patients were most likely to benefit from the use of the m-Health and apps compared to other age groups. However, this review found inadequate data to support the effectiveness of the app interventions for T1D patients with no statistically significant beneficial outcomes in trials comparing HbA1c between m-Health apps and intervention groups (Hou et al, 2016).

Another recent meta-analysis of mobile health interventions for those with T2D in 13 studies with a total of 1022 patients concluded that m-Health app-based self-management shows moderate benefits on blood glucose control with a pooled effect on HbA1c reduction of -0.40% (-4.37 mmol/mol) (Liang et al, 2011). From these two recent meta-analyses, it seems that there are significant benefits to controlling blood glucose levels arising from use of m-Health apps, especially in those with T2D using oral medication or in the context of their lifestyle behaviour.

Recent studies have also shown that mobile short message service (SMS) interventions (text messaging'), can provide a simple yet effective approach for improving education and communication for people with diabetes. Several RCTs and pilot studies of SMS interventions to support diabetes self-

management have been conducted in different countries (Haddad et al, 2014; Hall et al, 2015). The clinical outcomes from these SMS studies provide preliminary evidence to suggest the clinical impact and effectiveness of mobile SMS interventions in improving diabetes care outcomes but further studies are required.

Discussion

There is increasing evidence of the clinical impact and cost-effectiveness of m-Health and smartphone-centric approaches for diabetes care. However, there are unmet needs for diabetes care especially in T2D for which m-Health interventions, if designed and developed correctly, may provide better outcomes.

These include:

- The increasing requirement for practical approaches to prevention of onset of diabetes through screening for pre-diabetes
- The need for more innovative approaches to achieving better HbA1c targets
- The need for better prevention of disease progression and complications
- The need to improve patient adherence
- The requirement to support dietetic education for patients.

However, there are several barriers to this approach that can be generally categorised from the patient and care provider's perspectives. These include socioeconomic, psychosocial, physical and environmental factors that may be perceived by individuals to influence their ability to perform adequate self-care activities. For the healthcare provider, these barriers relate primarily to cost, privacy, security, cultural and policy issues (Istepanian and Woodward, 2017).

From the business perspective, it is estimated that there are currently more than 1200 diabetes smart apps in the market (Istepanian and Woodward, 2017). This trend is likely to increase, with the possibility of the emergence of the 'diabetes apps prescriptions' culture driven by the market push in this area. Most of these commercial diabetes apps available in the market today are designed and developed for narrow segments of the market with specific tasks and few supplemented with clinical or pilot studies.

Furthermore, with most of these apps, the role of the healthcare provider is missing, with most developed as tools acting as electronic logbooks for the patient's blood glucose monitoring levels. Moreover, few of these offer effective intelligent coaching and behavioural self-management functionalities that can provide much better and long-term management and usability mechanisms (Diabetes UK, 2013). Most of the current re-imbursement models for mobile diabetes care are developed in the USA and are unlikely to be applied in low resource countries where their healthcare delivery provisions and economic models are different.

There are also many clinical uncertainties associated with the m-Health interventions for diabetes self-management. These can be summarised as follows:

- There is increasing debate on the clinical effectiveness of mobile SMBG interventions, supplemented by a lack of large clinically robust m-Health studies and RCTs in this area. Adequately powered, well-designed studies are much needed to evaluate their clinical effectiveness. Those studies that have been published evaluated the effect of the intervention on primary outcomes, such as HbA1c, body mass index, weight and blood pressure. Such studies should also measure the effect

on secondary outcomes, e.g. impact on lifestyle change, long-term usability and adherence, social and behavioural change, care barriers and cost effectiveness

- There are so far no detailed clinical studies of the impact of mobile phone interventions on obese individuals with diabetes (so-called 'diabesity')
- Identification of suitable smart m-Health educational models that translate the standards of diabetes care into protocols suitable for different ethnic or resource settings
- The role of incentives in facilitating behavioural change by appropriate smart educational tools is not yet well understood or fully realised
- The challenges of cyber-security and privacy concerns and the ownership of large health data sets generated by social networking and apps
- The development of alternative business models and ecosystems for creating a new generation of m-Health diabetes care models. These might be based on recent technological advances and not solely based on smartphonecentric care models (Istepanian and Woodward, 2017).

Conclusion

In recent years there has been increasing interest in developing m-Health approaches for diabetes self-care and management. These are usually referred to as smartphone-based diabetes self management or 'digital diabetes'. Although the smartphone app business and supporting industry have been much-hyped, there has not been the equivalent development of clinical evidence to back the use of this technology.

It seems very likely that these technologies will become the norm in diabetes self care in the near future. However, to achieve this goal, more clinical studies focusing on the most effective outcomes that may impact the health and wellbeing of individuals with diabetes are needed. The use of these m-Health technologies for diabetes should also be applied to individuals with diabetes in the developing world, where their impact may be greater due to the resource challenges of delivering high-quality care. The need to develop more frugal m-Health methods for diabetes care that are affordable, correctly aligned to the economic environment, and better tailored to the social and cultural requirements of patients in these areas is vital for the future success of these technologies in this important area. This is crucial for widening the usage spectrum and the role of mobile health for diabetes care, especially in low income and low resource countries beyond the current 'traditional' smartphone-centric models.

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